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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,361	12/03/2001	Flohe Leopold	9300008-2005	9710
20999	7590	02/02/2004	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,361	Applicant(s) LEOPOLD ET AL.	
	Examiner Ralph Gitomer	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The preliminary amendment received 8/13/01 has been entered and claims 1-8 are currently pending in this application. The priority papers have been received and priority is granted to 3/9/1999. Please update the specification accordingly. No form 1449 is found in the file but there are a number of references found, all of which are cited herein.

The references cited of record do not teach or fairly suggest the presently claimed step of determining latent PHGPx by reactivating with thiols.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 8 is directed to use of a method which is improper.

Claims 1, 4-7 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The limitations of claim 2 are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In the specification on page 7 lines 13-15, removing denaturing and reducing agents is required prior to determining PHGPx activity. This step is not found in claims 1, 4-7.

Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1(b) "using high concentrations" is improper because no concentrations are recited and use of concentrations is not understood. In claim 4 line 3, "re-activated" lacks antecedent basis and may be intended to be "reactivated".

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: No Figures 5 and 6 are found and there is no Brief Description of the Drawings presented. Please provide all the standard headings. On page 12 line 26 there appears to be a trademarked reagent, generic terminology should accompany the trademark name in all occurrences. Appropriate correction is required.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Roveri (Methods in Enzymology) teaches determining membrane bound hydroperoxide glutathione peroxidase.

Maiorino (Methods in Enzymology) teaches determining hydroperoxide glutathione peroxidase.

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* 5,895,749

Alvarez (WO 96/13225) teaches determining sperm enzymes to determine fertility.

Maiorino (FASEB) teaches determining glutathione peroxidase in testes.

Ursini (Science) teaches sperm maturation and PHGPx.

~~Roveri (Methods in Enzymology) teaches membrane bound hydroperoxide glutathione peroxidase.~~

Hillman (6,231,853) teaches glutathione peroxidases.

Maurer (Z Ernährungswiss) teaches determining glutathione peroxidases.

Godeas (Biology of Reproduction) teaches free and bound PHGPx.

Roveri (Biochimica et Biophysica Acta) teaches determining PHGPx.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Ralph Gitomer
Primary Examiner
Art Unit 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200